PCT/AU00/00665

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I, KAY WARD, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ 1006 for a patent by CARDIAC CRC NOMINEES PTY LTD filed on 17 June 1999.

I further certify that the above application is now proceeding in the name of NORTHERN SYDNEY AREA HEALTH SERVICE pursuant to the provisions of Section 113 of the Patents Act 1990.

WITNESS my hand this
Twenty-ninth day of June 2000

K Ward

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AUSTRALIA

Patents Act 1990

~~Cardiac CRC Nominees Pty Ltd~~
Northern Sydney Area Health Service

PROVISIONAL SPECIFICATION

Invention Title:

An assist device for the failing heart

The invention is described in the following statement:

An assist device for the failing heart

Field of the Invention

The present invention relates to a device and method for assisting a failing heart.

Background Art

Cardiac compression has been used to boost a failing heart for many years and in its most simple life-saving form involves the compression of the chest wall of a patient and thus the compression of the heart muscle itself. In an emergency situation, a medical practitioner may take this one step further and manually compress a heart that has failed until recovery or an alternative treatment may be commenced.

Of course, not all patients present in an acute state and typically a heart will be damaged over a period of time. Such is the case in heart failure which occurs when the heart fails to maintain sufficient circulation to provide adequate tissue oxygenation. Heart failure is widespread in the community, affecting, for example, 5 million Americans at any one time. Despite recent advances in cardiology, it also remains on the increase due to an ageing population.

Mechanical heart assist devices that can be used to boost an ailing heart have the potential to provide a quality of treatment that seriously challenges current treatment options, including heart transplantation. Whilst heart transplantation is quite effective in patients with severe heart failure, the shortage of donor hearts, the expense of the operation and post-operative care, and the risk of rejection are all major drawbacks to this option ever realistically meeting community expectations.

Several mechanical devices have been developed, one of which is the subject of US Patent No 5119804 to Anstadt. This device comprises a cardiac massage cup adapted to fit loosely over a lower portion of a heart. A diaphragm is positioned internal the cup and positive and negative pressure applied to the space between the diaphragm and the cup to alternately inflate

and deflate the diaphragm. When the diaphragm is inflated, the heart is squeezed to simulate systolic action (ejection of blood from the ventricles of the heart). The diaphragm is deflated to correspond with diastole (relaxing of the heart muscle and filling of the heart pumping chambers with blood). The cup itself is held in place around the heart by a suction force which prevents the heart from dislodging when compressive pressure is applied to the heart.

The requirement that the diaphragm be set inside a cup results in a bulky device which may also cause damage to the heart muscle, coronary circulation and the surrounding tissue.

Variations of the Anstadt cup have been developed including the device subject of US Patent No 5713954 which describes a cuff to enclose the lower regions of the heart. The cuff comprises a series of closed tubes which may be hydraulically or pneumatically inflated in time with the natural contractions of the heart to reinforce the contractile forces required to eject sufficient blood for the needs of the body.

A drawback of several assist devices is that the right and left ventricular pumping action of the heart is simulated using a single diaphragm. It is well recognised, however, that differences exist between right and left ventricular output and that right and left ventricular pressures are different. Essentially, because the left ventricle is ejecting blood to the entire body it requires a greater contractility. Devices with only one diaphragm will not assist to provide optimum output of either the right or the left ventricle. A device designed to address this problem is described in US Patent No 5749839 to Kovacs wherein the assist device is provided with two independently operated diaphragms within a cup to allow for independent control of the left and the right ventricles. This device does not seem, however, to take into account the difference in curvature between the surface of the left and right ventricles and uses a diaphragm of the same shape for both ventricles. This would seem to potentially result in a misfit of the device over the heart if used in this manner.

With the cardiac assist devices described above, there must be a means for securing the device to the external surface of a heart. Securement may be achieved by applying suction through a vacuum line, such as is the case in the Anstadt device, wrapping the device in a passive mesh which may be fitted around the heart, by suturing or by some form of adhesive. Whichever means is employed, there is a risk of damage to the heart and in particular to the coronary circulation which is made up of a network of blood vessels that traverse the outer surface of the heart.

In International Application No PCT/AU98/00433 (WO 98/55165) entitled "Cardiac Assist Device", a device comprising a cup and an internal diaphragm wherein at least a portion of the diaphragm is made from a biointegrating material is described. This device is designed to maximise affixation of the device to the heart by enabling vascularised tissue infiltration into the device. Preferably, the biointegrating material of the diaphragm integrates with the surface of the heart muscle to such an extent that a vacuum or other such means of securement is not required. It is believed that the use of a biointegrating material on the surface of the diaphragm minimises the risk of infection, and rejection of the device by the host's defence system. The device is reliant, however, on a bulky, cup-like structure and requires traditional surgical technique for placement. Such devices may also constrict the heart causing impairment of its filling and proper relaxation. This may also impede blood supply to the heart muscle via the coronary circulation.

Disclosure of the Invention

In a first aspect, the present invention provides a heart assist device including a heart engaging means having at least one paddle, the paddle including a first heart compressing surface adapted to be affixed to at least a region of the heart, and a second surface that is adapted to be distal said region of the heart, and wherein the heart compressing surface is movable in a direction relatively away from the second surface to compress at least said

region of the heart thereby assisting contraction of the heart muscle during systole, the heart compressing surface of the paddle being adapted to remain affixed with at least said region of the heart throughout operation of the device.

In a preferred embodiment, the heart compressing surface is adapted to remain affixed with at least said region of the heart regardless of any variation in the heart's condition.

As described, previously known devices for assisting a failing heart have relied upon the principle of partially encasing at least the lower regions of a heart in a cup or other similarly rigid device. Internal the cup, such devices have a membrane or diaphragm which may be activated to compress the heart. One problem associated with such devices is related to obtaining the best fit of the device to a heart that is already enlarged and flaccid. When the heart is so enlarged, the device in being placed around the heart can create a situation similar to constrictive pericarditis or cardiac tamponade, conditions which can cause severe impairment of the heart's pumping action due to external restriction that compromises filling of the blood chambers. This condition is likely to worsen when a layer of fibrous tissue is caused to grow around the heart because of a tissue reaction in response to the surrounding foreign material. When the device is of such a size that the heart is fitted too loosely in the cup, the pumping action of the diaphragm acts to thump the surface of the heart during systolic assist. This poses a threat of bruising the heart.

According to available evidence from clinical and experimental use of mechanical cardiac assist devices, it is likely that the heart will become smaller (a process termed reverse remodelling of the heart) as a result of their use. This process involves some recovery of the muscular cells of the heart allowing the heart chambers to revert towards a more favourable pumping geometry. With use of a rigid cup employing a one piece diaphragm or several linked chambers to secure compression of the heart, reverse

remodelling is unlikely to be facilitated even if the diaphragm is affixed to the heart. Further, if the diaphragm is affixed to the heart with this implementation, it is likely to hinder the efficient compression of the heart.

On the other hand, using individual paddles and affixing the heart compressing surface of the paddles to the heart surface in a manner that accommodates the improvement in heart condition that occurs with reverse remodelling is important. Means of affixing the heart compressing surface to the heart surface are discussed in more detail below.

In one embodiment, a majority of the heart compressing surface is affixed with at least said region of the heart. In a further embodiment, the entire heart compressing surface can be affixed to at least said region of the heart.

In one embodiment, the first heart compressing surface and the second surface define an interior therebetween that is variable in volume, with the variation arising from relative movement of the heart compressing surface to the second surface.

In a still further embodiment, the interior is in fluid communication with a driving means. The fluid communication between the interior and the driving means can be provided by a pipe or tube extending between the driving means and the paddle interior.

The shape of the paddles can be adjusted to suit the region of the heart to which the paddle is to be affixed. In one embodiment, each paddle can be substantially triangular in shape. The pipe or tube extending between the driving means and the paddle interior is preferably joined to the paddle adjacent an apex of the paddle.

The paddle can be curved relative to a notional lateral and/or longitudinal plane. The curvature of the paddle is preferably selected to suit the curvature of the region of the heart to which the paddle is to be affixed. In one embodiment, where the heart is considered to be an ellipsoid of revolution of the general form:

$$b^2x^2 + a^2y^2 + a^2z^2 = a^2b^2,$$

the paddle can have radii of curvature as defined by the following formulae:

$$R_1 = (R_2{}^3b^2)/a^4, \text{ and}$$

$$R_2 = (a^4y^2 + b^4x^2)^{3/2}/b^2$$

where

R_1 and R_2 represent the radii of the largest and smallest circles which are mutually perpendicular with centres on the normal to the surface;

a represents the major semi-axis of the ellipsoid; and

b represents the minor semi-axis of the ellipsoid.

In another embodiment, activation of the driving means causes the application of fluid pressure to the interior so causing the heart compressing surface to move relatively away from the second surface of the paddle.

In another embodiment, fluid pressure is applied to the interior by the driving means such that both the first compressing surface and the second surface are each caused to move in a direction relatively away from one another.

In another embodiment, the first compressing surface and the second surface of the paddle can be each made from a different material or the same material.

In yet a further embodiment, the heart compressing surface of the paddle is made from a material that is relatively more resiliently flexible than the material of the second surface. In this embodiment, the application of fluid pressure to the interior of the paddle causes a greater deflection of the first heart compressing surface than the second surface. In another

embodiment, the first and second surface are made from the same material but with different degrees of stiffness.

In a further embodiment, the fluid pressure is generated by a driving means that is positioned external to the body of a patient receiving the heart assist device.

In another embodiment, the driving means is located internal the body of the patient. In this embodiment, the driving means can be reduced to a size suitable for surgical implantation within the chest cavity of a patient.

In a further embodiment, the fluid pressure is generated from a pneumatic driving means.

In a still further embodiment, the fluid pressure is generated from a hydraulic driving means.

In another embodiment, the pressure generated from the driving means is in the range of 10 to 100mmHg. More preferably, the pressure generated is in the range of 20 to 60mmHg.

In a further embodiment, at least a portion of the heart compressing surface of the paddle includes a material which facilitates the ingrowth of vascularised cellular tissue elements into the paddle. The ingrowth of tissue into the heart compressing surface serves to affix the heart compressing surface of the paddle to the heart.

In another embodiment, the second surface may also be treated with a substance that promotes vascularised cellular ingrowth. In this embodiment, the second surface will integrate into the surrounding tissue thereby reducing the likelihood of bacterial infection or mechanical damage to the surrounding tissue.

In a further embodiment, the first heart compressing surface and/or the second surface may be treated with Seare Biomatrix™ or Gore-Tex DualMesh Biomaterial™.

In yet a further embodiment, the heart compressing surface may have one or more slits formed therein that preferably extend longitudinally of the

surface. In this embodiment, the slits are in a closed configuration during compression of the heart by the heart compressing of the paddle. Following compression of the heart and as the heart relaxes during the phase of diastole, the slits widen effectively increasing the surface area of the heart compressing surface. In this way, the slits serve to provide allowance for the contraction and distension of the heart during systole and diastole, respectively.

In still yet a further embodiment, at least a portion of the heart compressing surface can be concertinaed. This structure of the heart compressing surface serves to ensure maintenance of contact between the heart compressing surface and the region of the heart to which it is affixed during deflection of the surface relative to the second surface.

In a further embodiment, the paddle may be capable of undergoing a change from a first configuration to a second configuration. For example, the paddle may be capable of changing from a compressed configuration, in which configuration it is suitable for insertion into the patient's body, to an expanded configuration in which the paddle is ready for affixation to the surface of the heart.

In a further embodiment, the at least one paddle includes a shape memory material, such as polyurethane.

In a still further embodiment, the shape memory material can be Nitinol™.

In a still further embodiment, the heart compressing surface of the at least one paddle is engagable with a portion of the surface of the left ventricle of a heart.

In another embodiment, the heart compressing surface of the at least one paddle is engagable with a portion of the surface of the right ventricle of a heart.

In a further embodiment, the pressure applied to the interior of a paddle whose first heart compressing surface is in engagement with a left ventricle of a heart is in the region of 20 to 60mmHg.

In another embodiment, the pressure applied to the interior of a paddle whose first heart compressing surface is in engagement with a right ventricle of a heart is in the region of 20 to 45mmHg.

In a further embodiment, the heart compressing surface of the at least one paddle may be positioned anywhere on the surface of the heart. Accordingly, the paddle may be optimally placed, for example against the surface of the left ventricle to assist in systole of a heart. In a particularly preferred embodiment, the paddle may be positioned to allow compression of the heart from the apex to the base of the heart.

In another embodiment, the device may comprise multiple paddles that are connected to each other in a manner that still facilitates variations in the shape and configuration of the heart. In one particularly preferred embodiment, the device comprises two paddles flexibly connected to one another, wherein the heart compressing surface of one of the paddles engages with at least a portion of the surface of the left ventricle and the heart compressing surface of the second paddle engages with at least a portion of the surface of the right ventricle.

In another embodiment, straps are used to connect individual paddles. The straps can be made of absorbable materials. The paddles and interconnecting straps pass around the circumference of the heart with the compressing surfaces of the paddles in the appropriate position on the heart. This configuration provides efficient transfer of compression force to the cardiac chambers during the initial period after implantation and before the biomatrix material is firmly biointegrated with the heart surface. The biodegradable straps are resorbed by the body/tissue within one to four weeks, when the paddle-heart biointegration has become strong enough for the purpose of cardiac assist.

In one embodiment, an increase in fluid pressure may be applied to the interior of a first paddle independent of the pressure applied to the interior of the second paddle.

In a further embodiment, the paddle is shaped such that when affixed with the surface of the heart, the paddle avoids contact with any coronary artery bypass grafts present on the surface of the heart.

In a further embodiment, the device may be held in place against the surface of the heart at least initially by a covering means wrapped around the heart and the device. A suitable tissue glue may also be used alone or in conjunction with the covering means to assist affixation of the heart compressing surface to the heart surface.

In a still further embodiment, the device may be held in place initially by inserting the paddle between the heart surface and the surrounding pericardium. In this embodiment, the second surface of the paddle may be attached, for example by way of suturing, to the visceral pericardium. Alternatively, the paddle may be stitched in an incision of the pericardium such that it acts as a patch on the pericardium.

In another embodiment, the heart assist device further includes a means to monitor the natural cycle of a heart.

In a still further embodiment, the heart assist device may be activated during systole or diastole of the heart. The assist device can, for example, be activated in early systole or alternatively in late systole. Preferably, the heart assist device is activated throughout systole.

In a preferred embodiment, the monitoring means is an electrocardiogram (ECG). In this embodiment, an ECG electrode is connected to at least a region of the surface of a heart and the electrical signals received from the ECG electrode transmitted to a cardiotachometer for the detection of heart rate or beat-to-beat interval (in milliseconds). Exponential and derivative enhancement techniques are used to assure discrimination of the ECG's R-wave. Wide dynamic gain range and

adjustable latency time prevent false triggering. The natural heart rate is used in a feedback loop to control intensity of heart assist. If predetermined heart rate limits are exceeded the control system automatically switches to fixed rate assist. Specifications of this part of the control system include the following: (1) usable rate range 10 to 500 beats per minute (bpm) (2) usable interval range 1ms to 10s (3) measurement resolution 1ms (interval), 0.1 bpm (rate) (4) latency time adjustment range from 50ms to 1s or more. The monitoring of the heart in this way enables the heart assist device to be activated or deactivated at a particular desired time in the natural cycle of a heart.

In another embodiment, the paddle has mounted thereto at least one, and preferably a plurality of, sensors adapted to measure the heart dimensions during the cardiac cycle. In one embodiment, each paddle may have between 1 and 10 sensors. In one embodiment, the sensors may be piezoelectric sensors. The piezoelectric sensors can be formed from a piezoelectric crystal or piezoelectric plastics material (eg. polyvinylidene fluoride). In the case of a crystal, the surface area of each sensor is preferably about $1mm^2$. The sensors can provide a signal output to a signal receiving means. The signal receiving means can be located internal or external the body. If required, a power source for the sensors can also be provided internal or external the body. The signals of the sensors can be detected by the signal receiving means using a signal communication system. The communication system can also be used to activate the sensors such that they only provide signal outputs on demand.

The signals once received by the signal receiving means can be transmitted through a data transmission network for analysis at a distal location. For example, a physician could arrange for the download of signals of the sensors of the device of a patient over the data transmission network and provide an analysis of these signals without any requirement for the patient to visit the physician.

The dimensions measured by the sensors might include ventricular dimensions, including end-systolic and end-diastolic dimensions, segmental dimensions and cross-sectional dimensions. By the measurement of such dimensions, the signal receiving means or another device using signals output by the signal receiving means can be used to determine heart performance characteristics, including the ventricular volume, stroke volume, ejection fraction percentage and cardiac output of the heart.

The sensors can be used to monitor variation in heart performance in response to different sequences of deflection of the paddles of the device. This can be used to allow determination of the optimal sequence of deflection of the paddles and also allow the device to vary the sequence in response to changes in the heart cycle. The sequence of deflection of the paddles of the device can be adjusted in a number of ways, including:

- the ratio of assisted to non-assisted beats; and
- the electromechanical delay between native atrial (electrical) heart activation and deflection of the paddles.

The signals output by the sensors may also be used to set and adjust the degree of pressurisation of the paddles and the rate of rise and decay of pressure in the paddles.

Optimisation of the settings of the paddle pressurisation can be done in response to (a) exercise performed by the patient in the presence of a physician or (b) by pacing the heart using an ECG electrode attached to the heart. The ECG electrode may be typically implanted at the time of paddle implantation or may be already in place. A pacemaker that is inserted under the skin of the patient can be used to provide the necessary stimulation to the ECG electrode to pace the heart. The electrical stimulation of the pacemaker, when it is implanted, can be used as the trigger for the pressurisation sequence of the paddles.

In a second aspect, the present invention provides a method of assisting a failing heart using the heart assist device as defined herein, the method including the steps of:

(a) positioning the heart compressing surface of the paddle of the device at least adjacent a region of the heart;

(b) affixing the heart compressing surface of the paddle with the region of the heart; and

(c) applying fluid pressure to the interior of the paddle such that the heart compressing surface compresses the heart muscle in the region of the heart that is affixed to the surface.

In a third aspect, the present invention provides a method of introducing a paddle of the device as defined herein to the heart of a patient, the method including the steps of:

(a) making an incision or puncture in the chest of a patient to allow access to the heart;

(b) inserting the paddle through the incision or puncture;

(c) affixing the heart compressing surface of the paddle to a region of the heart; and

(d) applying fluid pressure to the interior of the paddle such that the heart compressing surface compresses the heart muscle in the region of the heart that is affixed to the surface.

In one embodiment of the third aspect of the invention, the paddle is inserted by firstly inserting a cannula through a port in the body and then passing the paddle through the cannula. In this embodiment, the paddle is preferably in a first closed configuration at least while it is internal the cannula. When positioned adjacent the region of the heart with which the paddle is to be affixed, the paddle is ejected from the cannula by a push rod or other like device whereupon it can take on a second expanded configuration. The cannula can then be withdrawn through the port before it is in turn removed.

In another embodiment of the third aspect of the invention, the paddle may initially be held in place by a covering means such as a mesh that will wrap around the paddle and the heart. If desired, a suitable tissue glue can also be used to either affix the heart compressing surface to the heart or to enhance affixation provided by the covering means. Once sufficient cellular ingrowth has occurred, the covering means may be removed from around the heart. Alternatively, the covering means may be made from a biocompatible resiliently flexible material which may remain in place around the heart and the paddle. It is important that the covering means is made from a suitable flexible material, however, to allow for any change in the heart's condition, including variation in its size, shape or configuration. In a still further embodiment, the covering means may be made from a biodegradable material that is progressively resorbed by the body over a period of time.

The paddle in all aspects of the invention is preferably adapted such that it may be introduced into the patient and proximate the heart using minimally invasive or endoscopic surgery. It will, however, be appreciated that the paddle may be introduced through any sized thoracotomy.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the following drawings:

Figure 1 is a schematic representation of a heart with two devices according to the present invention in position against the surface of the heart.

Figure 2 is a plan view of one surface of the device of the invention.

Figure 3 is a cross-sectional view through I-I of Figure 2 depicting the device of the invention in a collapsed state.

Figure 4 is a cross-sectional view through I-I of Figure 2 depicting the device of the invention in an expanded state.

Figure 5a is a plan view of one embodiment of the invention.

Figure 5b is an end view of the embodiment of invention depicted in Figure 5a in a collapsed state.

Figure 5c is a cross-sectional view of the embodiment of the invention depicted in Figure 5a in an expanded state.

Figure 6a is a plan view of a further embodiment of the invention.

Figure 6b is an end view of the embodiment of the invention depicted in Figure 6a in a collapsed state.

Figure 6c is a cross-sectional view of the embodiment of the invention depicted in Figure 6a in an expanded state.

Figure 7 is a longitudinal cross-sectional view of a further embodiment of the invention.

Figure 8 is a graph showing the effect of the device of the present invention on left ventricular pressure and left ventricular volume in a normal sheep heart.

Best Mode of Carrying out the Invention

In one embodiment of the invention, heart assist device 10 comprises a paddle 11 having a first surface 12 which is adapted to be affixed to a region of the surface of a heart and a second surface 13 which is positioned distal the surface of the heart.

A portion 14 of the first surface 12 is made from a more resiliently flexible material than the material of the remainder of the first surface 12 and the second surface 13.

The first surface 12 and second surface 13 of paddle 11 define an interior 15 therebetween. Interior 15 is in fluid communication with a driver (not shown) which generates either hydraulic or pneumatic pressure. When the driver is activated pressure builds up in interior 15 causing both surface 12 and surface 13 to be moved relatively away from one another. The driver can be positioned either internal or external the body of a patient receiving the paddle 11. Because portion 14 of first surface 12 is made from a relatively more resiliently flexible material, it undergoes a greater deflection

than the remainder of the first surface 12 and the second surface 13 upon the application of pressure. The result is that the first surface 12 is caused to relatively deflect to a greater degree than surface 13. As first surface 12 is affixed to the surface of the heart, the deflection of the first surface 12 causes compression of the heart by paddle 11. Alternatively, the entire surface 12 may be made from a relatively more resiliently flexible material than the material of surface 13.

The deflection of the first surface 12 relative second surface 13 is depicted in Figures 3 and 4. Figure 3 shows paddle 11 in a collapsed state and Figure 4 shows paddle 11 in an expanded state. An interior 15 has been included in Figure 3 for clarity purposes however it could readily be envisaged that, in a collapsed state, the first surface 12 and second surface 13 of paddle 11 could collapse back against one another and substantially occlude interior 15.

Interior 15 is in fluid communication with the driver by way of tube 20 which is made from a suitably resiliently flexible material to facilitate insertion of the paddle 11 into the chest cavity of a patient whist still maintaining its tubular shape. This is an important feature as any kinking of the tube would block the communication between interior 15 and the driver thereby preventing the application of pressure to the surfaces of paddle 11.

Where a portion of the first surface comprises a resiliently flexible material, the remainder of surface 12 may be made from a biointegrating material which facilitates the ingrowth of vascularised cellular tissue elements into the paddle 11. The cellular ingrowth of tissue secures the paddle to the surface of the heart avoiding the need to use suturing or various adhesives. In addition to securing the paddle 11 to the surface of the heart, the likelihood of rejection of paddle 11 by the heart and surrounding tissue is also reduced. Furthermore, because the heart tissue biointegrates with the paddle there is a markedly lessened chance of 'fibrous capsule' formation and the incidence of infection is greatly reduced. This is an important feature as

30% of failures of mechanical assist devices result from infection. Surface 13 may also be made from the same biointegrating material as the first surface 12.

In use, a single paddle may be applied to the surface of a heart or, alternatively, multiple paddles may be positioned around the surface of the heart. As depicted in Figure 1, a first paddle 16 is positioned against the surface of the left ventricle 17 of a heart 18. A second paddle 19 is positioned against the surface of the right ventricle 21 of heart 18. The ability to place an individual paddle adjacent a specific portion of a heart is of great significance especially when it is understood that the chambers of the heart differ considerably in both function and anatomy.

The left ventricle is the chamber of the heart which receives oxygenated blood from the lungs. The function of the left ventricle is to pump this oxygenated blood to the entire body which requires a great force of ejection. The blood inside the left ventricle is therefore under a much greater pressure than in the right ventricle (about six times higher), the right ventricle simply having to pump de-oxygenated blood as far as the lungs. To obtain a sufficient ejection of blood, the muscular wall of the left ventricle must vigorously contract against the blood filled chamber. Accordingly, the walls of the left ventricle are much thicker and in fact, about three times thicker than the walls of the right ventricle.

If a device is to provide adequate assistance to a failing left ventricle it must apply a sufficient force upon the ventricle to eject a volume of blood at a sufficient pressure to reach the entire body. On the other hand, a failing right ventricle requires much less force to eject the blood within the chamber to the lungs.

The present invention enables separate and individually controlled paddles 11 to be positioned against the right and the left ventricles. Accordingly, more pressure may be applied to paddle 16 positioned on the left ventricle 17 than paddle 19 positioned on the right ventricle 21.

The anatomy of the left and right ventricles also differs substantially. In cross-section, the left ventricle is circular whereas the right ventricle is crescentic due to the bulging of the interventricular septum (the wall which divides the left and the right ventricles) into the cavity of the right ventricle. The difference in anatomy of the two ventricles calls for a particular structure of paddle to ensure optimal fit and performance. Figures 5a, 5b, and 5c and 6a, 6b and 6c show the difference in shape of paddles for use in respect of either the left or the right ventricles. Paddle 16 is adapted to be positioned against the left ventricle whereas paddle 19 is adapted for placement against the surface of the right ventricle. The arc formed by paddle 16 is less than the arc formed by paddle 19 as depicted in Figures 5b and 6b and thus is adapted to securely engage with the surface of the left ventricle.

In use, the paddle 11 is small enough to be inserted by endoscopic or some other form of minimally invasive surgery. The paddle 11 may be made from a material that can adopt several different configurations and in preferred embodiments, the paddle 11 may be constructed of a 'shape memory' flexible material such as polyurethane or it may include within its structure a memory shape material, such as a Nitinol™ wire, threaded around its periphery. The paddle may be inserted into a cannula or some other delivery device in a closed configuration. The cannula is then introduced into the chest cavity through a puncture or incision and when in position adjacent the portion of heart to be assisted, the paddle is disposed from the end of the cannula. Once free of the cannula, the paddle 11 takes on an expanded configuration such that the first surface 12 is caused to engage with the adjacent portion of heart.

When the paddle 11 is in place proximate the heart, an elastic mesh (not shown) or other like flexible material may be placed around the heart thereby initially securing the paddle 11 to the heart surface. The elastic mesh may be removed upon integration of the heart tissue with the paddle

11. Alternatively, the mesh may be made from a biodegradable material which over time will be broken down and resorbed by the body.

Figure 7 shows a further embodiment of the invention wherein the first surface 12 is concertinaed or rippled. The rippled surface serves to ensure maintenance of contact between the first surface 12 and the region of the heart to which it is affixed during deflection of the first surface 12 relative to the second surface 13. Figure 7 shows the positioning of the first surface 12 during diastole of the heart and, in phantom, the positioning of the first surface 12 during systole.

The heart assist device as depicted herein may be activated during systole or diastole of the heart. The assist device can be activated in early systole, in late systole, or throughout systole.

The device can include a monitoring means that monitors the natural cycle of the heart of the patient. Such a monitoring means can be an electrocardiogram (ECG). In this case, an ECG electrode is connected to at least a region of the surface of a heart and the electrical signals received from the ECG electrode transmitted to a cardiotachometer for the detection of heart rate or beat-to-beat interval (in milliseconds). Exponential and derivative enhancement techniques are used to assure discrimination of the ECG's R-wave. Wide dynamic gain range and adjustable latency time prevent false triggering. The natural heart rate is used in a feedback loop to control intensity of heart assist. If predetermined heart rate limits are exceeded the control system automatically switches to fixed rate assist. Specifications of this part of the control system include the following: (1) usable rate range 10 to 500 beats per minute (bpm) (2) usable interval range 1ms to 10s (3) measurement resolution 1ms (interval), 0.1 bpm (rate) (4) latency time adjustment range from 50ms to 1s or more. The monitoring of the heart in this way enables the heart assist device to be activated or deactivated at a particular desired time in the natural cycle of a heart.

In an embodiment of the device not depicted, the paddle has mounted thereto a plurality of piezoelectric sensors (normally between 2 and 10) adapted to measure the heart dimensions during the cardiac cycle. The piezoelectric sensors can be formed from a piezoelectric crystal or piezoelectric plastics material (eg. polyvinylidene fluoride). In the case of a crystal, the surface area of each sensor is preferably about $1mm^2$. The sensors provide a signal output to a signal receiving means, that like the driver can be located internal or external the body. If required, a power source for the sensors can also be provided internal or external the body. The signals of the sensors can be detected by the signal receiving means using a signal communication system. The communication system could also be used to activate the sensors such that they only provide signal outputs on demand.

If required, the signals once received by the signal receiving means can be transmitted through a data transmission network for analysis at a distal location. For example, a physician could arrange for the download of signals of the sensors of the device of a patient over the data transmission network and provide an analysis of these signals without any requirement for the patient to visit the physician.

The dimensions measured by the sensors might include ventricular dimensions, including end-systolic and end-diastolic dimensions, segmental dimensions and cross-sectional dimensions. By the measurement of such dimensions, the signal receiving means or another device using signals output by the signal receiving means can be used to determine heart performance characteristics, including the ventricular volume, stroke volume, ejection fraction percentage and cardiac output of the heart.

The sensors can be used to monitor variation in heart performance in response to different sequences of deflection of the paddles of the device. This can be used to allow determination of the optimal sequence of deflection of the paddles and also allow the device to vary the sequence in

response to changes in the heart cycle. The sequence of deflection of the paddles of the device can be adjusted in a number of ways, including:

- the ratio of assisted to non-assisted beats; and
- the electromechanical delay between native atrial (electrical) heart activation and deflection of the paddles.

The signals output by the sensors may also be used to set and adjust the degree of pressurisation of the paddles and the rate of rise and decay of pressure in the paddles.

Optimisation of the settings of the paddle pressurisation can be done in response to (a) exercise performed by the patient in the presence of a physician or (b) by pacing the heart using an ECG electrode attached to the heart. The ECG electrode may be typically implanted at the time of paddle implantation or may be already in place. A pacemaker that is inserted under the skin of the patient can be used to provide the necessary stimulation to the ECG electrode to pace the heart. The electrical stimulation of the pacemaker when it is implanted, can also be used as the trigger for the pressurisation sequence of the paddles.

Figure 8 shows the effect of the heart assist device 10 upon both the pressure in the left ventricle and the left ventricular volume. This particular example demonstrates the effect of the assist device 10 on a normal sheep's heart wherein the assist device is activated every three heart beats. Figure 8 shows that the assist device 10 increases the ejection of blood from the left ventricle (ejection fraction). This improved performance of the left ventricle is coupled with an increase in the peak pressure generated in that chamber.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

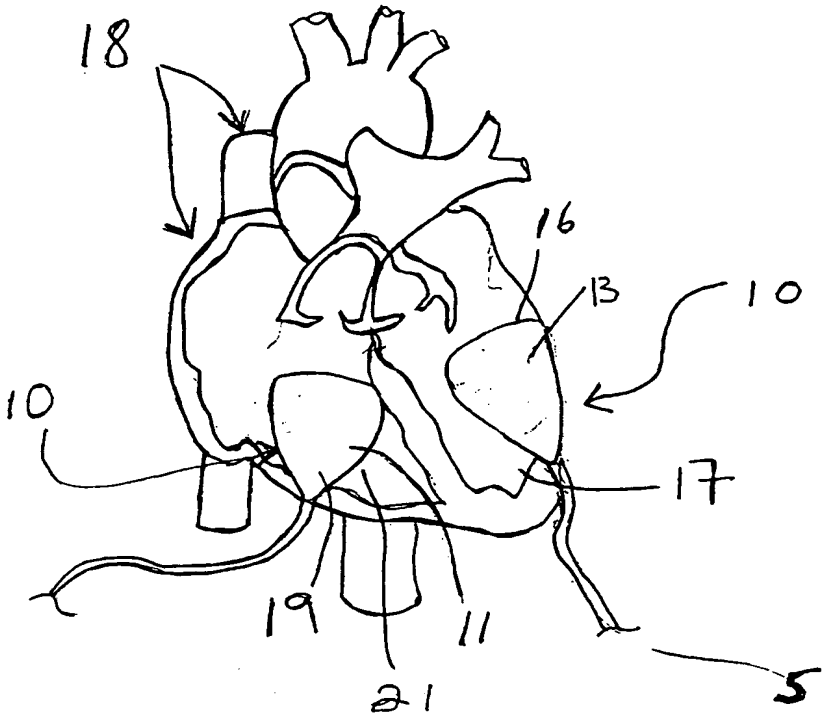
Dated this seventeenth day of June 1999

Northern Sydney Area Health Service
~~Cardiac CRC Nominees Pty Ltd~~

Patent Attorneys for the Applicant:

F B RICE & CO.

Fig. 1



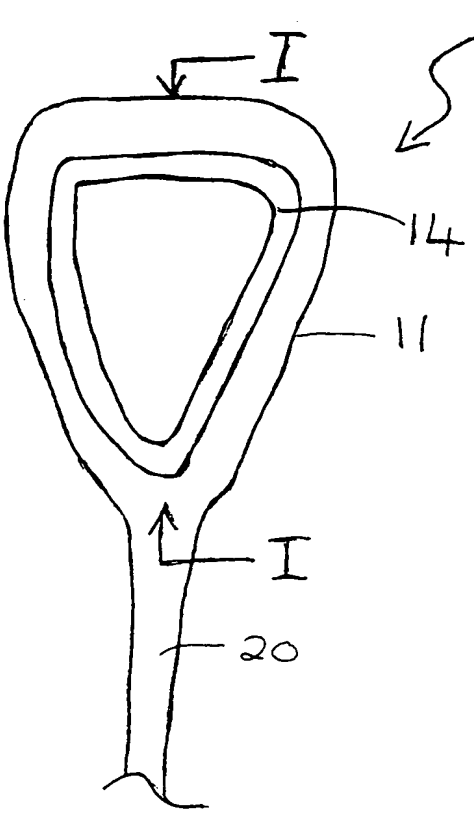


Fig 2

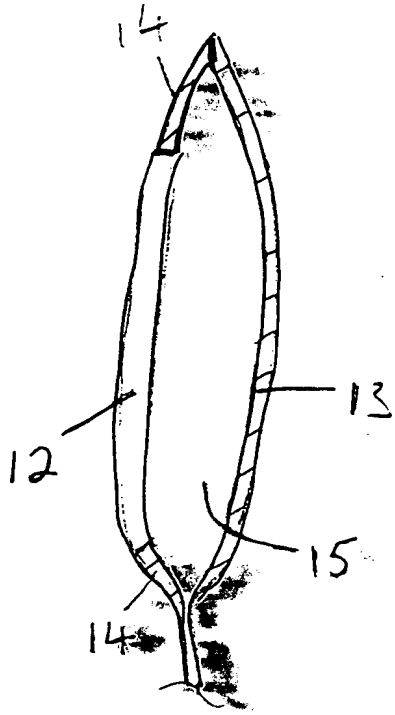


Fig 3

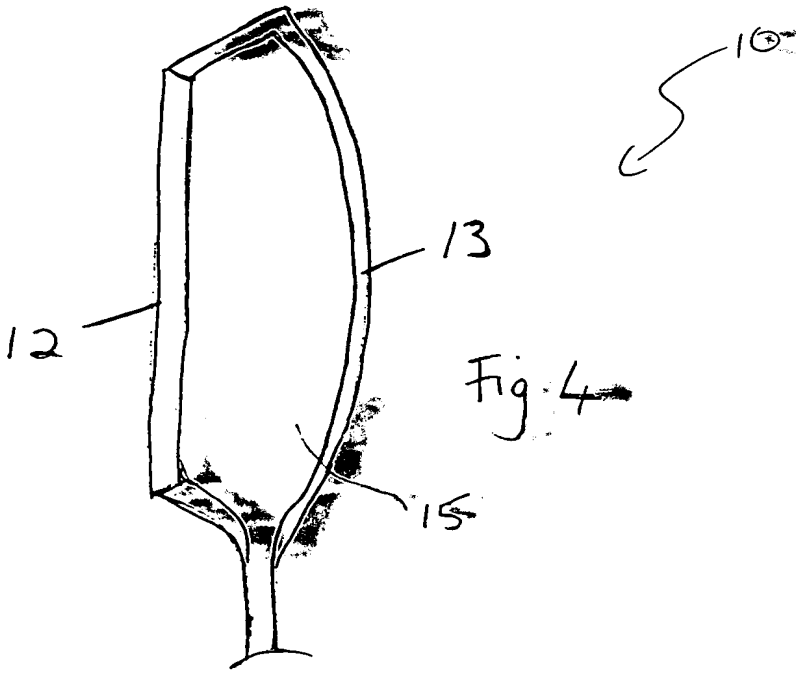


Fig 4

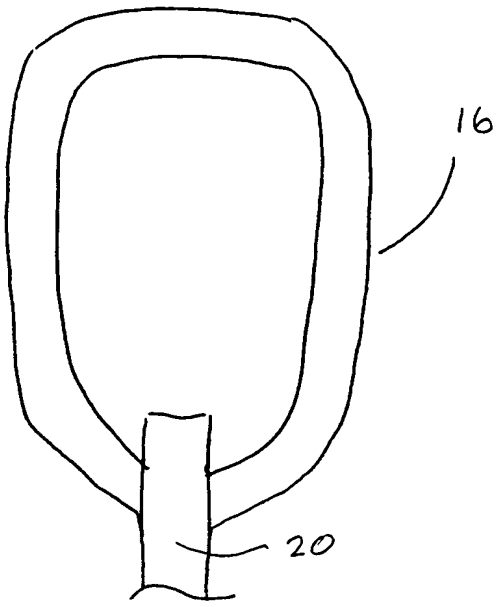


Fig 5a

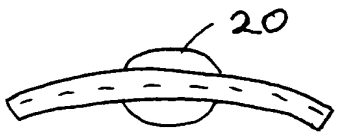


Fig 5b

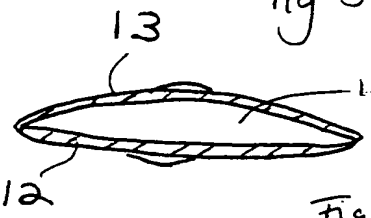


Fig 5c

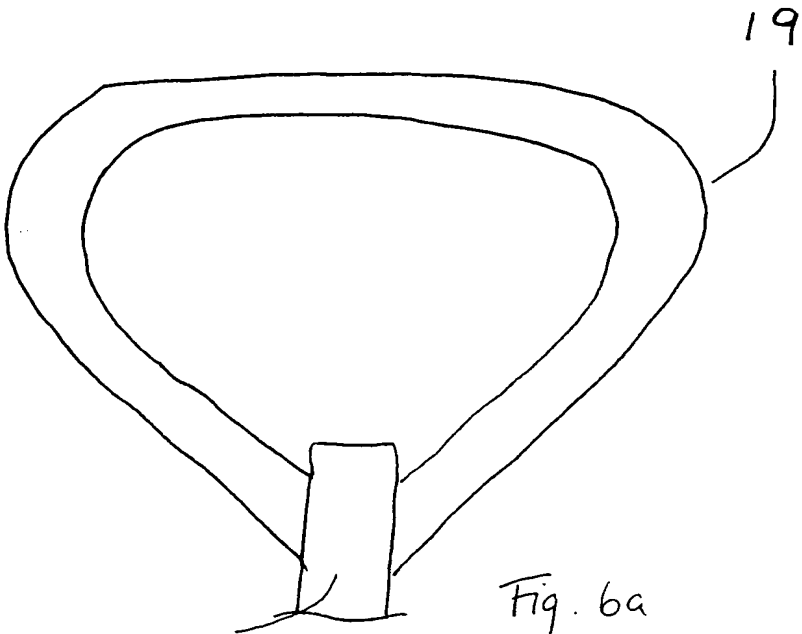


Fig. 6a

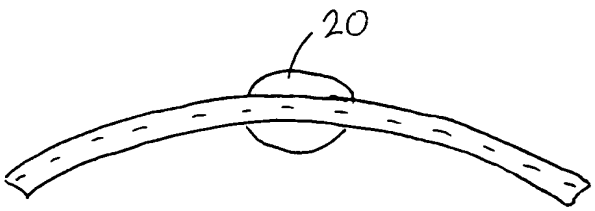


Fig 6b

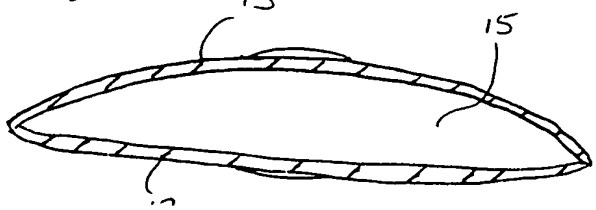


Fig 6c

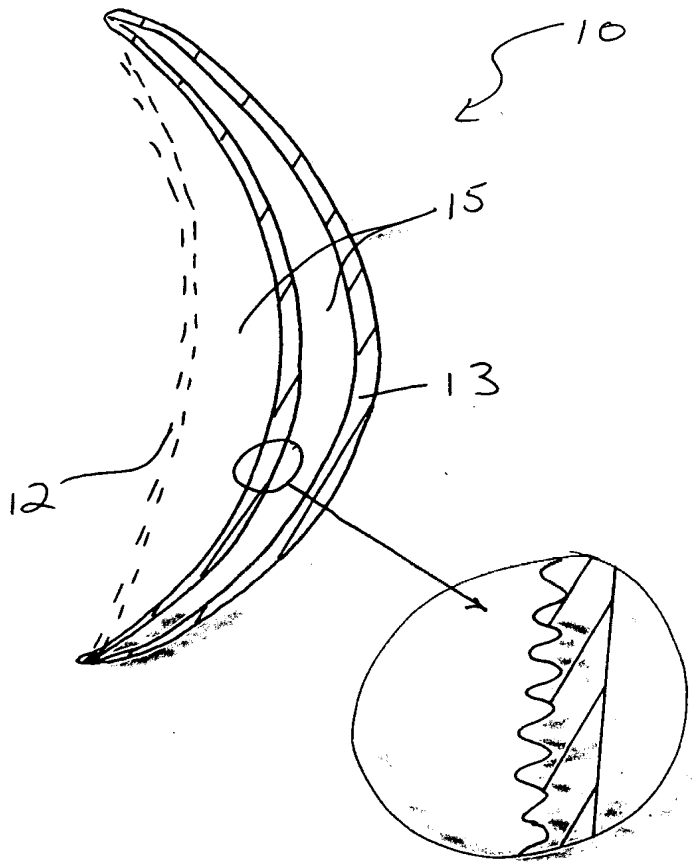


Figure 7.

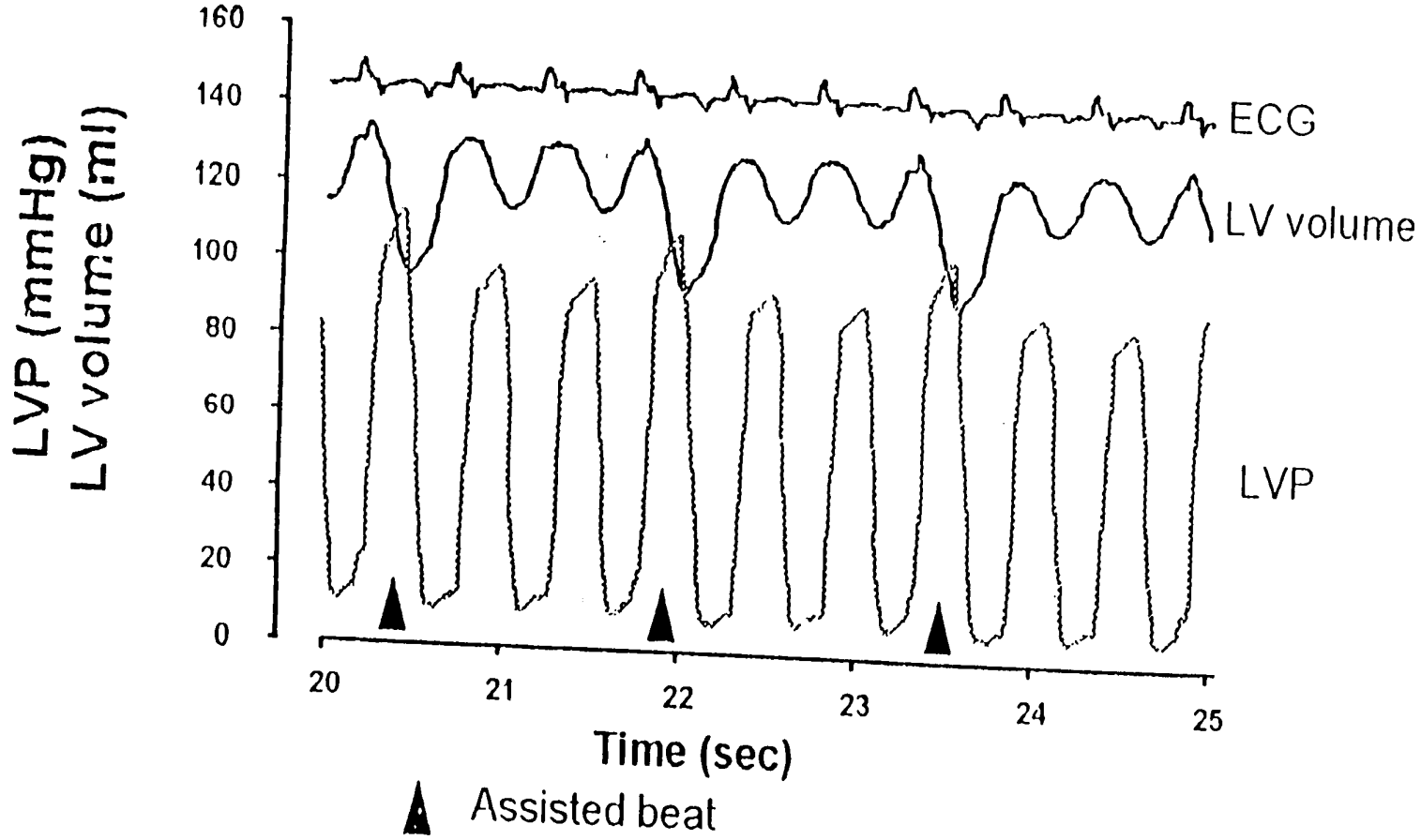

LVP (mmHg)
LV volume (ml)
160
140
120
100
80
60
40
20
0
ECG
LV volume
LVP
20
21
22
23
24
25
Time (sec)
Assisted beat

Figure 8

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